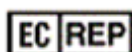




For professional use only

## STOR-F transport medium

### INSTRUCTION FOR USE



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P-901-1/1EU

P-901-R/1EU

P-901-N/1EU



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## TABLE OF CONTENTS

<b>1. INTENDED USE</b>	<b>3</b>
<b>2. METHOD</b>	<b>3</b>
<b>3. CONTENT</b>	<b>3</b>
<b>4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED</b>	<b>3</b>
<b>5. STORAGE AND HANDLING REQUIREMENTS</b>	<b>4</b>
<b>6. WARNINGS AND PRECAUTIONS</b>	<b>4</b>
<b>7. SAMPLES</b>	<b>6</b>
<b>8. PROCEDURE</b>	<b>6</b>
<b>9. SPECIFICATIONS</b>	<b>7</b>
<b>10. QUALITY CONTROL</b>	<b>7</b>
<b>11. KEY TO SYMBOLS</b>	<b>9</b>

## 1. INTENDED USE

The **STOR-F transport medium** is intended for transport and storage of human biological samples (scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye) followed by nucleic acids analysis (human DNA, DNA of microorganisms, RNA of viruses) by polymerase chain reaction method.

This medical device is an auxiliary agent in clinical laboratory diagnostics and is intended for transport and storage of human biological samples, followed by nucleic acids analysis by polymerase chain reaction method.

The application of the kit does not depend on population and demographic aspects. There are no contradictions for use of the **STOR-F transport medium**.

The **STOR-F transport medium** can be used in clinical and diagnostic laboratories of medical institutions and research practice.

Potential users: personnel qualified in molecular diagnostics methods and working in the clinical and diagnostic laboratory.

It is necessary to apply the kit only as directed in this instruction for use.

## 2. METHOD

The **STOR-F transport medium** is a ready-to-use isotonic water-salt solution with the addition of a preservative, which prevents the growth of microorganisms.

## 3. CONTENT

The detailed description of content is represented in Tables 1-3.

Table 1. The **STOR-F transport medium** content, package S, tubes for P-901-1/1EU

Reagent	Description	Total volume	Amount
Transport medium	Colorless transparent liquid	50 mL (500 µL in each)	100 tubes

Table 2. The **STOR-F transport medium** content, package S, screw cap tubes for P-901-R/1EU

Reagent	Description	Total volume	Amount
Transport medium	Colorless transparent liquid	50 mL (500 µL in each)	100 tubes

Table 3. The **STOR-F transport medium** content, package N for P-901-N/1EU

Reagent	Description	Total volume	Amount
Transport medium	Colorless transparent liquid	50 mL (25 mL in each)	2 vials

All components are ready to use and do not require additional preparation for operation.

The kit in packages S, tubes, and S, screw cap tubes, are intended for single use and designed for 100 tests for **STOR-F transport medium**.

The kit in package N is designed for 100 tests for **STOR-F transport medium**.

## 4. REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

### 4.1. Specimen collection

- Sterile single use swabs, cytobrushes, cotton swabs e.t.c for sampling of biomaterial;
- 1.5 mL tubes (only for work with package N).

### 4.2. Preparation for DNA extraction

- Biological safety cabinet class II;
- Refrigerator;
- Vortex mixer;
- High speed centrifuge (RCF(g) 13000);
- Tube rack for 1.5 mL tubes;
- Single channel pipettes (dispensers covering 100-1000 µL volume range);
- RNase and DNase free filtered pipette tips (volume 1000 µL);
- NA extraction kit;
- Container for used pipette tips, tubes and other consumables;
- Powder-free surgical gloves;
- Disinfectant solution.

## 5. TRANSPORT AND STORAGE CONDITIONS

Expiry date – 12 months from the date of production.

The **STOR-F transport medium** must be transported in thermoboxes with ice packs by all types of roofed transport at temperatures inside the thermoboxes corresponding to storage conditions of the kit components.

It is allowed to transport the kit in thermoboxes with ice packs by all types of roofed transport at temperatures from 2 °C to 25 °C inside the thermoboxes, but for no longer than 14 days.

Kits transported with violation of temperature conditions must not be used.

All components of the **STOR-F transport medium** must be stored in a refrigerator or a cooling chamber at temperatures from 2 °C to 8 °C over the storage period.

The excessive temperature and light can be detrimental to product performance.

Shelf-life of the kit following the first opening of the primary container: the components of the kit must be stored in a refrigerator or a cooling chamber at temperatures from 2 °C to 8 °C over the storage period.

The kit stored under undue regime must not be used.

An expired **STOR-F transport medium** must not be used.

We strongly recommend to follow the given instructions in order to obtain accurate and reliable results.

The conformity of the **STOR-F transport medium** to the prescribed technical requirements is subject to compliance of storage, transportation and handling conditions recommended by manufacturer.

Contact our official representative in EU by quality issues of the **STOR-F transport medium**.

## 6. WARNINGS AND PRECAUTIONS

Only personnel trained in the methods of molecular diagnostics and the rules of work in the clinical and diagnostic laboratory are allowed to work with the kit.

Handle and dispose all biological samples, reagents and materials used to carry out the assay as if they were able to transmit infective agents. The samples must be exclusively employed for certain type of analysis. Samples must be handled under a laminar flow hood. Tubes containing different samples must never be opened at the same time. Pipettes used to handle samples must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA. The reagents must be handled under a laminar flow hood. The reagents required for amplification must be

prepared in such a way that they can be used in a single session. Pipettes used to handle reagents must be exclusively employed for this specific purpose. The pipettes must be of the positive dispensation type or be used with aerosol filter tips. The tips employed must be sterile, free from the DNases and RNases, free from DNA and RNA. Avoid direct contact with the biological samples reagents and materials used to carry out the assay. Wear powder-free surgical gloves. Wear protective clothing (work clothes and personal protective equipment) working with microorganisms classified as particularly pathogenic. The protective clothing and personal protective equipment must comply with the work to be performed and health and safety requirements. Avoid producing spills or aerosol. Any material being exposed to biological samples must be treated for at least 30 minutes with disinfecting solution or autoclaved for 1 hour at 121 °C before disposal.

Molecular biology procedures, such as nucleic acids extraction, reverse transcription, PCR-amplification and detection require qualified staff to avoid the risk of erroneous results, especially due to the degradation of nucleic acids contained in the samples or sample contamination by amplification products.

All the liquid solutions are designed for single use and can not be used more than once in amplification reactions. Plastic tubes do not contain phthalates. Do not breathe gas/fumes/vapor/spray produced by the components of the kit. Do not eat/drink components of the kit. Avoid contact with eyes. Only use the reagents provided in the kit and those recommended by manufacturer. Do not mix reagents from different batches. Do not use reagents from third party manufacturers' kits. All laboratory equipment, including pipettes, test tube racks, laboratory glassware, lab coats, bouffant caps, etc., as well as reagents should be strictly stationary. It is not allowed to move them from one room to another. Equip separate areas for the extraction/preparation of amplification reactions and for the amplification/detection of amplification products. Never introduce an amplification product in the area designed for extraction/preparation of amplification reactions. Wear lab coats, gloves and tools, which are exclusively employed for the extraction/preparation of the amplification reaction and for the amplification/detection of the amplification products. Never transfer lab coats, gloves and tools from the area designed for amplification/detection of the amplification products to the area designed for extraction/preparation of amplification reactions. Remove waste materials (tubes, tips) only in a special closed container containing a disinfectant solution. Work surfaces, as well as rooms where NA extraction and PCR are performed, must be irradiated with bactericidal irradiators for 30 minutes before and after the work.

Waste materials are disposed of in accordance with local and national standards. All surfaces in the laboratory (work tables, test tube racks, equipment, etc.) must be treated daily with disinfecting solution.

### **Emergency actions**

**Eye Contact:** If any component of this kit enters the eyes, wash eyes gently under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

**Skin Contact:** If any component of this kit contacts the skin and causes discomfort, remove any contaminated clothing. Wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.

**Ingestion:** If any component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, obtain medical attention.

Do not use the kit:

- When the transportation and storage conditions are breached;
- When the reagents' appearance does not respond to the kit passport;
- When the kit components packaging is breached;
- After the expiry date provided.

Significant health effects are **NOT** anticipated from routine use of this kit when adhering to the instructions listed in the current manual.

## 7. SAMPLES

The **STOR-F transport medium** is designed to transport and storage the scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye.

### General requirements

Remove free separable mucus with a sterile cotton prior to sampling. In case of sampling from several locations, repeat the procedure several times, each time taking a new swab into new different tube.

To prevent contamination, open the tube, add sample, then close the tube before proceeding to the next sample.

### Package S

Transport medium is ready for use.

### Package N

Mark necessary number of 1.5 mL tubes. Add 500 µL of transport medium into marked tubes. Close the tubes tightly.

**ATTENTION!** It is recommended that during the first opening of the bottle (package N), the transport medium should be added to all 50 tubes. Prepared tubes should be stored at temperatures from 2 °C to 8 °C for the entire shelf life, and used when necessary.

### Scrapes/smears of epithelial cells sampling

Order of taking:

1. Open the 1.5 mL tube with **STOR-F transport medium**.
2. Scrape epithelial cells from the corresponding biotope (i.e. urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye) with a sterile swab.
3. Put the swab into the tube with transport medium and rinse it thoroughly. Avoid spraying of solution.
4. Remove swab from solution, press it to the wall of tube and squeeze the rest of the liquid. Throw out the swab.
5. Close the tube tightly and mark it.

### Transportation and storage of the samples

Transport and store samples in **STOR-F transport medium** at temperatures from 2 °C to 8 °C for no longer than 7 days.

Transport and store samples in **STOR-F transport medium** at temperatures from 18 °C to 25 °C is acceptable for no longer than 48 hours.

## 8. PROCEDURE

### 8.1. General recommendations

1. Use only disposable RNase and DNase free filtered pipette tips.
2. When adding the solution into sample, do not touch the walls of the tubes with the tip. If the tip has touched the wall of the tube, change the tip. Tip should be changed each time when you take out solution from the tube with sample.
3. To prevent contamination, open the tube, add sample/reagent, then close the tube before proceeding to the next sample/reagent.

## 8.2. Preparation for NA extraction

8.2.1 Centrifuge samples in transport medium at RCF(g) 13,000 for 10 minutes.

8.2.2 Remove supernatant, leaving the volume recommended by NA extraction kit (precipitate+liquid fraction) from this kind of sample.

**ATTENTION!** If for sample pretreatment centrifugation is not needed, p.8.2.1 and 8.2.2 are not performed.

**ATTENTION!** For scrape/smear from oropharynx and nasopharynx for subsequent analysis of viral RNA, preliminary centrifugation is not required.

8.2.3 Perform NA extraction according to NA extraction kit user manual.

8.2.4 To make a negative control perform p. 8.2.1 and 8.2.2 for tube with **STOR-F transport medium** which does not contain sample. Or use necessary volume of saline as sample according to NA extraction kit manual.

**STOR-F transport medium** is compatible with any NA extraction methods.

## 9. SPECIFICATIONS

Parameter	Storage conditions	
	48 hours under temperatures from 18 °C to 25 °C	7 days under temperatures from 2 °C to 8 °C
	Average, 95% CI*	
Preservation of human genomic DNA (%), calculated for 50 samples	87.9 (83.9 – 92.0)	86.3 (80.2 – 92.5)
Preservation of viral nucleic acids (detected by <b>AVRI</b> kit <sup>1</sup> ) (%), calculated for 21 samples	97.6 (91.5 – 100)	79.9 (67.8 – 92.1)
*95% CI - 95% confidence interval		

The preservation of nucleic acids in biomaterial samples in the **STOR-F transport medium** was estimated as the relative amount of nucleic acids (%) in the samples after storage in the transport medium at different temperature-time regimes compared to samples without storage, calculated using the indicator cycle comparison method ( $\Delta C_p$ ) in real-time PCR reaction.

## 10. QUALITY CONTROL

“DNA-Technology Research&Production”, LLC declares that the abovementioned products meet the provision of the Regulation (EU) 2017/746 of the European parliament and of the Council of 5 April 2017. The quality control procedures performed in accordance with ISO 9001:2015 and ISO 13485:2016:

- observation of quality management in manufacturing of IVDD products;
- creation of values for customers;
- maintenance of the best service quality and customer management.

Contact our official representative in EU by quality issues of **STOR-F transport medium**.

<sup>1</sup> - **Acute viral respiratory infections Real-Time PCR Detection Kit** (“DNA-Technology Research&Production”, LLC)

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11. KEY TO SYMBOLS

	<i>In vitro</i> diagnostic medical device		Manufacturer
	Temperature limit		Date of manufacture
	Contains sufficient for <n> tests		Consult instructions for use
	Use-by date		Catalogue number
	Batch code		Version
	Authorized representative in the European Community		Non-sterile
	Do not re-use		



P-901-1/1EU

P-901-R/1EU



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